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HB
12/28/01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of)

BERNDL et al.)

BOX PCT

PCT/EP 00/02382)

Intl. Filing Date: March 17, 2000)

US Serial No.: TO BE ASSIGNED)

For: SOLUBILIZING EXCIPIENTS IN POWDER FORM FOR SOLID
PHARMACEUTICAL PRESENTATIONS

Honorable Commissioner of
Patents and Trademarks
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Sir:

Prior to examination of the above-identified U.S. National
Stage application, kindly amend the application as follows.

09/937313

CLEAN VERSION OF ALL CLAIMS

1. An excipient in powder form for use in solid pharmaceutical presentations, comprising a pharmaceutically acceptable polymer and a liquid or semisolid solubilizing surface-active substance.

2. An excipient as claimed in claim 1, comprising a surface-active substance with a drop point in the range from 20 to 40°C.

3. (amended) An excipient as claimed in claim 1, comprising a surface-active substance with an HLB of from 10 to 15.

4. (amended) An excipient as claimed in claim 1, comprising as pharmaceutically acceptable polymer a homo- or copolymer of N-vinylpyrrolidone.

5. (amended) An excipient as claimed in claim 1, comprising more than 10 and up to 70% by weight of the surface-active substance.

6. (amended) An excipient as claimed in claim 1, comprising ethoxylated sorbitan fatty acid esters as surface-active substances.

7. (amended) An excipient as claimed in claim 1, comprising products of the reaction of ethylene oxide with castor oil, hydrogenated castor oil or with 12-hydroxystearic acid as surface-active substance.

8. (amended) A process for producing excipients in powder form as claimed in claim 1, which comprises spray-drying a solution comprising the surface-active substance and the pharmaceutically acceptable polymer.

9. (amended) A process for producing excipients as claimed in claim 1, which comprises processing the constituents to a homogeneous melt in an extruder, followed by shaping.

0050/49860-0001

MARKED-UP VERSION OF AMENDED CLAIMS

3. (amended) An excipient as claimed in [either of claims 1 and 2] claim 1, comprising a surface-active substance with an HLB of from 10 to 15.

4. (amended) An excipient as claimed in [any of claims 1 to 3] claim 1, comprising as pharmaceutically acceptable polymer a homo- or copolymer of N-vinylpyrrolidone.

5. (amended) An excipient as claimed in [any of claims 1 to 4] claim 1, comprising more than 10 and up to 70% by weight of the surface-active substance.

6. (amended) An excipient as claimed in [any of claims 1 to 5] claim 1, comprising ethoxylated sorbitan fatty acid esters as surface-active substances.

7. (amended) An excipient as claimed in [any of claims 1 to 6] claim 1, comprising products of the reaction of ethylene oxide with castor oil, hydrogenated castor oil or with 12-hydroxystearic acid as surface-active substance.

8. (amended) A process for producing excipients in powder form as claimed in [any of claims 1 to 7] claim 1, which comprises spray-drying a solution comprising the surface-active substance and the pharmaceutically acceptable polymer.

9. (amended) A process for producing excipients as claimed in [any of claims 1 to 7] claim 1, which comprises processing the

BERNDL et al., oz 0050/49860

constituents to a homogeneous melt in an extruder, followed by shaping.

0050/49860-0001